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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/552,354	10/06/2005	Keith M. Rosiello	350959-0004 THMX-001US	2403

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EXAMINER	
BOSWORTH, KAMI A	

ART UNIT	PAPER NUMBER
3767	

MAIL DATE	DELIVERY MODE
07/27/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/552,354	ROSIELLO ET AL.	
	Examiner	Art Unit	
	KAMI A. BOSWORTH	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 June 2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26,31 and 32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-26,31 and 32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *06 October 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/9/2011*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/9/2011 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1-9, 12-15, 17-19, 22, 24-26, 31 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ogawa (US Pat 4,680,445) in view of Swenson (US Pat 5,195,976).

4. Re claim 1, Ogawa discloses a system (Fig 1) for heating a fluid for delivery into a body of a patient (Abstract) comprising: an elongated fluid delivery-line (formed by inlet conduit 28, contents of housing 10, and outlet conduit 30, Fig 1) comprising: a tube 26 (Fig 3) for communicating a fluid (Col 3, Lines 32-35); three thermal sensors

54,56,58 (Fig 4), at least one thermal sensor 54,58 (Fig 4) positioned approximate to each end of the tube and at least one thermal sensor 56 (Fig 4) positioned in between the ends of the tube (Col 3, Lines 61-67; as seen in Fig 4); and a heating element 50,52 (Fig 4) positioned proximate a surface of the tube to heat fluid within the tube (Col 3, Lines 53-61), the heating element being controlled based on temperature data from the three thermal sensors to generate two determined heat gradients through the fluid within the tube (Col 5, Lines 24-63). Ogawa does not explicitly disclose that the delivery-line is flexible. Swenson, however, teaches an elongated flexible fluid delivery-line 30,40 (Fig 1B; Col 6, Lines 16-19) for the purpose of connecting a fluid reservoir to a point of entry into the patient (Col 4, Lines 23-25). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Ogawa to include a flexible fluid delivery line, as taught by Swenson, for the purpose of connecting a fluid reservoir to a point of entry into the patient (Col 4, Lines 23-25).

5. Re claim 2, Ogawa discloses a controller 60 (Fig 5).

6. Re claim 3, Ogawa discloses that the heating element is spaced apart from an outer surface of the tube (Col 3, Line 61 - Col 4, Line 2).

7. Re claim 4, Ogawa discloses that a wall of the tube comprises a thermal medium for distributing heat received by the outer surface of the tube from the heating element (Col 4, Lines 26-38).

8. Re claim 5, Ogawa discloses that the heating element surrounds the tube (as seen in Fig 4; Col 4, Lines 15-18).

9. Re claim 6, Ogawa discloses a heating element 50,52 (Fig 4) but does not discloses that the heating element spirally surrounds the tube. Swenson, however, teaches a heating element 43 (Fig 2) that spirally surrounds a tube 32 (Fig 2) for the purpose of heating an IV fluid (Col 11, Lines 49-51). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Ogawa to include a heating element that spirally surrounds the tube, as taught by Swenson, for the purpose of heating an IV fluid (Col 11, Lines 49-51).

10. Re claim 7, Ogawa discloses that the heating element comprises a plurality of heating elements 50,52 (Fig 4) surrounding the tube (Col 4, Lines 15-18) and having a length positioned substantially parallel to a length of the tube (as seen in Fig 4).

11. Re claim 8, Ogawa discloses that the heating element comprises a plurality of heating elements 50,52 (Fig 4) that are spaced apart from one another along a length of the tube (as seen in Fig 4) but does not disclose that each one circumferentially surrounds the tube. Swenson, however, teaches a plurality of heating elements 48 (Fig 3, 4) that circumferentially surround the tube (as seen in Fig 4), spaced apart from one another along a length substantially parallel to a length of tube 32 (Fig 3) for the purpose of heating an IV fluid (Col 6, Lines 42-48). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Ogawa to include a plurality of heating elements circumferentially surrounding the tube, as taught by Swenson, for the purpose of heating an IV fluid (Col 6, Lines 42-48).

12. Re claim 9, Ogawa discloses that the heating element is surrounded by a thermal medium (Col 4, Lines 26-38).

13. Re claim 12, Ogawa discloses all the claimed features except a transfusion needle and/or a luer lock at one end. Swenson, however, teaches a transfusion needle 33 (Fig 1B) at one end for the purpose of introducing the fluid into the body (Col 6, Lines 17-19). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Ogawa to include a transfusion needle, as taught by Swenson, for the purpose of introducing the fluid into the body (Col 6, Lines 17-19).

14. Re claim 13, Ogawa discloses that the heating element and/or the three thermal sensors are in electrical contact with the controller (Col 4, Lines 20-38; as seen in Fig 5).

15. Re claim 14, Ogawa discloses that the controller is connected to a power source (Col 3, Lines 51-52 and Col 5, Lines 21-23).

16. Re claim 15, Ogawa discloses a power source but does not explicitly disclose that the power source is selected from the group consisting of: a one-time use battery, pack, a rechargeable battery pack, AC power, and DC power. Swenson, however, teaches a substantially similar system for heating a fluid for delivery into a body comprising an AC power source (Col 7, Lines 29-31) for the purpose of powering system components (Col 7, Lines 26-31). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Ogawa to include an AC power source, as taught by Swenson, for the purpose of powering system components (Col 7, Lines 26-31).

17. Re claim 17, Ogawa discloses that the controller provides an electrical current to the heating element (Col 4, Lines 26-35 and Col 5, Line 64 - Col 6, Line 7).

18. Re claim 18, Ogawa discloses that the controller controls the temperature of the tube by sensing a temperature corresponding to a temperature of fluid within the tube and adjusting the amount of current supplied to the heating element (Col 4, Lines 26-35 and Col 5, Line 64 – Col 6, Line 7).

19. Re claim 19, Ogawa discloses a heat element connector and/or a thermal sensor connector for connecting the heat element and thermal sensor, respectively, to corresponding connectors on the controller (Col 4, Lines 27-28 and Col 4, Lines 31-35).

20. Re claim 22, Ogawa discloses a metering means for determining a flow rate of fluid traversing through the tube (Abstract).

21. Re claims 24-26, Ogawa discloses all the claimed features except an insulative tube and a thermal medium positioned between the insulative tube and the tube and enveloping the heating element. Swenson, however, teaches a thermal medium 46 (Fig 3) positioned between a tube 32 (Fig 3) and an insulative tube 47 (Fig 3) and enveloping a heating element 48 (Fig 3) for the purpose of keeping the IV fluid warm (Col 8, Lines 19-22). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Ogawa to include a thermal medium positioned between the delivery tube and an insulative tube and enveloping the heating element, as taught by Swenson, for the purpose of keeping the IV fluid warm (Col 8, Lines 19-22).

22. Re claim 31, Ogawa discloses a system (Fig 1) for heating a fluid for delivery into a body of a patient (Abstract) comprising: a controller 60 (Fig 5); and an elongated fluid delivery-line (formed by inlet conduit 28, contents of housing 10, and outlet conduit 30,

Fig 1) having a first end 28 (Fig 3) for receiving fluid from a fluid source and delivering the fluid to a destination (Col 3, Lines 32-35), the fluid delivery line comprising: an insulative body 48 (Fig 4); a fluid delivery tube 26 (Fig 4) positioned within the insulative body, the fluid delivery tube for communicating a fluid (Col 3, Lines 32-35); three thermal sensors 54,56,58 (Fig 4), at least one thermal sensor 54,58 (Fig 4) positioned proximate to each end of the fluid delivery tube and at least one thermal sensor 56 (Fig 4) positioned in between the ends of the tube (Col 3, Lines 61-67; as seen in Fig 4); a heating element 50,52 (Fig 4) positioned proximate the fluid delivery tube, the heating element being controlled based on temperature data from the three thermal sensors to generate two or more determined heat gradients through the fluid within the tube (Col 5, Lines 24-63). Ogawa does not disclose that the insulative body is a tube or that the thermal medium is positioned between the fluid delivery tube and an insulative tube. Swenson, however, teaches a thermal medium 46 (Fig 3) positioned between a tube 32 (Fig 3) and an insulative tube 47 (Fig 3) for the purpose of keeping the IV fluid warm (Col 8, Lines 19-22). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Ogawa to include a thermal medium positioned between the delivery tube and an insulative tube, as taught by Swenson, for the purpose of keeping the IV fluid warm (Col 8, Lines 19-22).

Ogawa also does not explicitly disclose that the delivery-line is flexible. Swenson, however, teaches an elongated flexible fluid delivery-line 30,40 (Fig 1B; Col 6, Lines 16-19) for the purpose of connecting a fluid reservoir to a point of entry into the patient (Col 4, Lines 23-25). Therefore, it would have been obvious to one of ordinary skill in the art

at the time the invention was made to modify Ogawa to include a flexible fluid delivery line, as taught by Swenson, for the purpose of connecting a fluid reservoir to a point of entry into the patient (Col 4, Lines 23-25).

23. Re claim 32, Ogawa discloses that the fluid deliver-line delivers the fluid to a destination at a measurable flow rate (Col 6, Lines 42-45) but does not explicitly disclose that it is a constant flow rate. Swenson, however, teaches delivering a heated fluid through a fluid delivery-line to a destination at a constant flow rate (Col 6, Lines 63-64) for the purpose of delivering fluid to the body in a controlled fashion (Col 6, Lines 61-64). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Ogawa to include a constant flow rate, as taught by Swenson, for the purpose of delivering fluid to the body in a controlled fashion (Col 6, Lines 61-64).

24. Claims 10 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ogawa (US Pat 4,680,445)/Swenson (US Pat 5,195,976) in view of Lenker (US Pat 6,746,439).

25. Re claim 10, Ogawa discloses a thermal medium but does not disclose that the thermal medium comprises a fluid. Lenker, however, teaches a delivery tube 146 (Fig 4) which has a thermal medium that comprises a fluid 158 (Col 7, Lines 9-12) for the purpose of transferring heat to the IV fluid (Col 7, Lines 37-40). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Ogawa/Swenson to include a thermal medium that comprises a fluid, as taught by Lenker, for the purpose of transferring heat to the IV fluid (Col 7, Lines 37-40).

26. Re claim 16, Ogawa/Swenson discloses all the claimed features except that the tube is sterile prior to use. Lenker, however, teaches that tube 146 (Fig 4) is sterile prior to use (Col 8, Lines 54-55) for the purpose of ensuring sterile contact between the device and a patient (Col 8, Lines 56-59). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Ogawa/Swenson to include a tube that is sterile prior to use, as taught by Lenker, for the purpose of ensuring sterile contact between the device and a patient (Col 8, Lines 54-59).

27. Claims 11 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ogawa (US Pat 4,680,445)/Swenson (US Pat 5,195,976) in view of Shigezawa (US Pat 6,641,556).

28. Re claim 11, Ogawa/Swenson discloses all the claimed features except that a bag spike. Shigezawa, however, teaches a substantially similar system for heating a fluid for delivery into a body (Abstract) comprising a fluid-delivery line (as seen in Fig 1) including a bag spike (as seen connected to drip chamber 106 in Fig 1) positioned at one end for the purpose of connecting the fluid-delivery line to a source of IV fluid (Col 3, Lines 9-13). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Ogawa/Swenson to include a bag spike, as taught by Shigezawa, for the purpose of connecting the fluid-delivery line to a source of IV fluid (Col 3, Lines 9-13).

29. Re claim 23, Ogawa/Swenson discloses all the claimed features except a heat-conductive member adjacent an interior portion of the tube and proximate the heating element. Shigezawa, however, teaches a heat-conductive member 132 (Fig 4) having a

first portion placed adjacent an interior portion of a tube 120 (Fig 4) and a second portion placed proximate a heating element 146 (Fig 4), wherein the heat-conductive material transfers heat from the heating element to the interior portion of the tube (Col 4, Lines 27-29) for the purpose of heating fluid continuously along the tube (Col 4, Lines 28-29). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Ogawa/Swenson to include a heat-conductive member adjacent an interior portion of the tube and proximate the heating element, as taught by Shigezawa, for the purpose of heating the fluid continuously along the tube (Col 4, Lines 28-29).

30. Claims 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ogawa (US Pat 4,680,445)/Swenson (US Pat 5,195,976) in view of Cassidy et al. (US Pat 6,175,688).

31. Re claims 20 and 21, Ogawa/Swenson discloses all the claimed features except a temperature actuated valve that opens upon the temperature of a fluid within the tube reaching a predetermined value. Cassidy et al., however, teaches a substantially similar device having a temperature actuated valve 702 (Fig 13) that opens upon the temperature of the fluid within the tube reaching a predetermined value (Col 13, Lines 1-36) for the purpose of protecting a patient from inadequate flow conditions in the line (Col 13, Lines 33-36). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Ogawa/Swenson to include a temperature actuated valve, as taught by Cassidy et al., for the purpose of protecting a patient from inadequate flow conditions in the line (Col 13, Lines 33-36).

Response to Arguments

32. Applicant's arguments filed 6/9/2011 have been fully considered but they are not persuasive.

33. In response to Applicant's argument that the case-type device of Ogawa is not a fluid delivery line, the Examiner respectfully disagrees. As cited in the present and previous rejection of the claims, Ogawa's inlet conduit 28, contents of housing 10, and outlet conduit 30 make-up the claimed "fluid delivery line" as they comprise tube 26, thermal sensors 54,56 and 58, and heating element 50,52. Applicant admits that the case-type warming device (made up of casing 10 and cover 40) "receives a fluid warming bag (element 26) through which fluid can flow"; because the case-type device forms the path through which fluid flows (as admitted by the Applicant), this case-type device of Ogawa reads on the "fluid delivery line" as presently claimed. One of ordinary skill in the art at the time the invention was made would recognize that a device through which fluid can flow reads on a “fluid delivery line” in the absence of any claimed features that further define this structure. Since Ogawa discloses the three components that comprise the fluid delivery line (a tube, three or more thermal sensor, and a heating element), the case-type device reads on the “fluid delivery line" as presently claimed. (No sufficient structure is claimed that eliminates this case type device from reading on the “fluid delivery line”. The feature that the “fluid delivery line” be flexible is taught by Swenson as cited in the above rejection.)

34. In response to Applicant's argument that the bag element 26 does not include three thermal sensors and therefore does not read on the claim, the Examiner respectfully disagrees. The Examiner has identified bag element 26 to read on the claimed "tube", not on the "fluid delivery line". As the claim is written, it is not the tube that comprises the sensors, but rather the fluid delivery line that comprises the sensors. Since sensors 54, 56 and 58 are found within housing 10 (which in combination with inlet conduit 28 and outlet conduit 30 make up the claimed "fluid delivery line"), the limitation "fluid delivery line comprising [...] three or more thermal sensors" is disclosed by Ogawa.

Conclusion

35. All claims are drawn to the same invention claimed in the application prior to the entry of the RCE submission under 37 CFR 1.114 and would have been properly finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to the filing of the RCE under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KAMI A. BOSWORTH whose telephone number is (571)270-5414. The examiner can normally be reached on Monday - Thursday, 8:00 am to 4:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/K. A. B./
Examiner, Art Unit 3767
/KEVIN C. SIRMONS/

Supervisory Patent Examiner, Art Unit 3767